

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.: 09-cv-00563-JFM
)	
LUPIN LTD., <i>et al.</i>)	
)	
Defendants.)	

PLAINTIFF'S ANSWER TO DEFENDANTS' COUNTERCLAIM

Plaintiff Genzyme Corporation ("Genzyme") for its answer to the counterclaim of Defendants Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Ltd. (collectively, "Lupin") hereby states as follows:

PARTIES

1. Lupin Ltd. is a company organized and existing under the laws of India, having a place of business at Laxmi Towers "B" Wing, 5th floor, Banda Kurla Complex, Mumbai 400 051, India.

ANSWER: On information and belief, Genzyme admits the allegations of paragraph 1.

2. LPI is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202.

ANSWER: On information and belief, Genzyme admits the allegations of paragraph 2.

3. Plaintiff/Counterclaim-Defendant purports to be a company organized and existing under the laws of the Commonwealth of Massachusetts, and having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

ANSWER: Genzyme is a company organized and existing under the laws of the Commonwealth of Massachusetts, and having a principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme denies any remaining allegations in paragraph 3.

JURISDICTION AND VENUE

4. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Genzyme admits that Lupin purports to state claims that arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Genzyme denies any remaining allegations in paragraph 4.

5. This Court has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Genzyme does not contest this Court's subject matter jurisdiction with respect to the '545, '775, '013, '846 and '151 patents, but does contest this Court's subject matter jurisdiction with respect to the '780 patent. Genzyme denies any remaining allegations in paragraph 5.

6. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because it has availed itself of the rights and privileges of this forum by suing Lupin in this District, and because Plaintiff/Counterclaim-Defendant conducts substantial business in, and has regular and systematic contacts with, this District.

ANSWER: Genzyme admits that this Court has personal jurisdiction over it for the purposes of Lupin's Counterclaim. Genzyme denies any remaining allegations in paragraph 6.

7. Venue is proper in this District under 28 U.S.C. §§ 1391 (b) and 1400(b).

ANSWER: Genzyme admits the allegations in paragraph 7.

PATENTS-IN-SUIT

8. On or about March 5, 1996, the U.S. Patent and Trademark Office (“PTO”) issued U.S. Patent No. 5,496,545 (“the ‘545 patent”), entitled “Phosphate-Binding Polymers for Oral Administration,” to Stephen R. Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides.

ANSWER: Genzyme admits the allegations in paragraph 8.

9. On or about September 16, 1997, the PTO issued U.S. Patent No. 5,667,775 (“the ‘775 patent”), entitled “Phosphate-Binding Polymers for Oral Administration,” to Stephen R. Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides.

ANSWER: Genzyme admits the allegations in paragraph 9.

10. On or about January 21, 2003, the PTO issued U.S. Patent No. 6,509,013 B1 (“the ‘013 patent”), entitled “Method of Making Phosphate-Binding Polymers for Oral Administration,” to Stephen R. Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides.

ANSWER: Genzyme admits the allegations in paragraph 10.

11. On or about May 11, 2004, the PTO issued U.S. Patent No. 6,733,780 B1 (“the ‘780 patent”), entitled “Direct Compression Polymer Tablet Core,” to Joseph Tyler and John S. Peterson.

ANSWER: Genzyme admits the allegations in paragraph 11.

12. On or about March 21, 2006, the PTO issued U.S. Patent No. 7,014,846 B2 (“the ‘846 patent”), entitled “Phosphate-Binding Polymers For Oral Administration,” to Stephen R. Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides.

ANSWER: Genzyme admits the allegations in paragraph 12.

13. On or about December 2, 2008, the PTO issued U.S. Patent No. 7,459,151 B2 (“the ‘151 patent”), entitled “Phosphate-Binding Polymers For Oral Administration,” to Stephen R. Holmes-Farley, W. Harry Mandeville, III and George M. Whitesides.

ANSWER: Genzyme admits the allegations in paragraph 13.

14. Plaintiff/Counterclaim-Defendant purports and claims to own, and to have the right to enforce, the ‘545, ‘775, ‘013, ‘780, ‘846 and ‘151 patents.

ANSWER: Genzyme admits that it owns, and has the right to enforce, the ‘545, ‘775, ‘013, ‘780, ‘846 and ‘151 patents. Genzyme denies any remaining allegations in paragraph 14.

15. On March 6, 2009, Plaintiff/Counterclaim-Defendant sued Lupin in this District alleging infringement of the ‘545, ‘775, ‘013, and ‘846 patents under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Genzyme admits the allegations in paragraph 15.

16. On May 22, 2009, Plaintiff/Counterclaim-Defendant filed the First Amended Complaint in this action alleging infringement of the ‘545, ‘775, ‘013, ‘846 and ‘151 patents under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Genzyme admits the allegations in paragraph 16.

COUNT I
(Declaratory Judgment of Non-Infringement of the ‘545 Patent)

17. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

18. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the ‘545 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the non-infringement of the ‘545 patent is a legal conclusion to which no response is required. To

the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the infringement of the '545 patent. Genzyme denies any remaining allegations in paragraph 18.

19. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '545 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 19.

20. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '545 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 20.

COUNT II
(Declaratory Judgment of Invalidity of the '545 Patent)

21. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

22. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiff/Counterclaim-Defendant regarding the invalidity of the '545 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the invalidity of the '545 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between

Genzyme and Lupin regarding the validity of the '545 patent. Genzyme denies any remaining allegations in paragraph 22.

23. The claims of the '545 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

ANSWER: Genzyme denies the allegations in paragraph 23.

24. Lupin is entitled to a judicial declaration that the claims of the '545 patent are invalid.

ANSWER: Genzyme denies the allegations in paragraph 24.

COUNT III
(Declaratory Judgment of Non-Infringement of the '775 Patent)

25. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

26. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the '775 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the non-infringement of the '775 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the infringement of the '775 patent. Genzyme denies any remaining allegations in paragraph 26.

27. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '775 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 27.

28. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '775 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 28.

COUNT IV
(Declaratory Judgment of Invalidity of the '775 Patent)

29. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

30. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiff/Counterclaim-Defendant regarding the invalidity of the '775 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the invalidity of the '775 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the validity of the '775 patent. Genzyme denies any remaining allegations in paragraph 30.

31. The claims of the '775 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

ANSWER: Genzyme denies the allegations in paragraph 31.

32. Lupin is entitled to a judicial declaration that the claims of the '775 patent are invalid.

ANSWER: Genzyme denies the allegations in paragraph 32.

COUNT V
(Declaratory Judgment of Non-Infringement of the '013 Patent)

33. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

34. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the '013 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the non-infringement of the '013 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the infringement of the '013 patent. Genzyme denies any remaining allegations in paragraph 34.

35. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '013 patent, either literally or under the doctrine of equivalents.

ANSWER: Genzyme denies the allegations in paragraph 35.

36. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '013 patent, either literally or under the doctrine of equivalents.

ANSWER: Genzyme denies the allegations in paragraph 36.

COUNT VI
(Declaratory Judgment of Invalidity of the '013 Patent)

37. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

38. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiff/Counterclaim-Defendant regarding the invalidity of the '013 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the invalidity of the '013 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the validity of the '013 patent. Genzyme denies any remaining allegations in paragraph 38.

39. The claims of the '013 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

ANSWER: Genzyme denies the allegations in paragraph 39.

40. Lupin is entitled to a judicial declaration that the claims of the '013 patent are invalid.

ANSWER: Genzyme denies the allegations in paragraph 40.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '780 Patent)

41. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme states that no response is required to the allegations in paragraph

41. Lupin has dismissed Count VII.

42. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the '780 patent.

ANSWER: Genzyme states that no response is required to the allegations in paragraph 42. Lupin has dismissed Count VII.

43. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '780 patent, either literally or under the doctrine of equivalents.

ANSWER: Genzyme states that no response is required to the allegations in paragraph 43. Lupin has dismissed Count VII.

44. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '780 patent, either literally or under the doctrine of equivalents.

ANSWER: Genzyme states that no response is required to the allegations in paragraph 44. Lupin has dismissed Count VII.

COUNT VIII
(Declaratory Judgment of Non-Infringement of the '846 Patent)

45. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

46. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the '846 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the non-infringement of the '846 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the infringement of the '846 patent. Genzyme denies any remaining allegations in paragraph 46.

47. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '846 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 47.

48. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '846 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 48.

COUNT IX
(Declaratory Judgment of Invalidity of the '846 Patent)

49. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

50. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiff/Counterclaim-Defendant regarding the invalidity of the '846 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the invalidity of the '846 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the validity of the '846 patent. Genzyme denies any remaining allegations in paragraph 50.

51. The claims of the '846 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

ANSWER: Genzyme denies the allegations in paragraph 51.

52. Lupin is entitled to a judicial declaration that the claims of the '846 patent are invalid.

ANSWER: Genzyme denies the allegations in paragraph 52.

COUNT X
(Declaratory Judgment of Non- Infringement of the '151 Patent)

53. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

54. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiff/Counterclaim-Defendant regarding non-infringement of the '151 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the non-infringement of the '151 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy

between Genzyme and Lupin regarding infringement of the '151 patent. Genzyme denies any remaining allegations in paragraph 54.

55. The manufacture, use, sale, offer for sale, or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '151 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 55.

56. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the drug product that is described in Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '151 patent, either directly or indirectly.

ANSWER: Genzyme denies the allegations in paragraph 56.

COUNT XI
(Declaratory Judgment of Invalidity of the '151 Patent)

57. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Genzyme repeats and realleges its Answers above as if fully set forth herein.

58. There is an actual, substantial, and continuing justiciable case or controversy between both Lupin and Plaintiff/Counterclaim-Defendant regarding the invalidity of the '151 patent.

ANSWER: Genzyme states that whether a case or controversy exists with respect to the invalidity of the '151 patent is a legal conclusion to which no response is required. To the extent that a further response is required, Genzyme states that there is a case or controversy between Genzyme and Lupin regarding the validity of the '151 patent. Genzyme denies any remaining allegations in paragraph 58.

59. The claims of the '151 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

ANSWER: Genzyme denies the allegations in paragraph 59.

60. Lupin is entitled to a judicial declaration that the claims of the '151 patent are invalid.

ANSWER: Genzyme denies the allegations in paragraph 60.

PRAYER FOR RELIEF

Genzyme denies that Lupin is entitled to any relief, either as prayed for in their Counterclaim or otherwise.

Genzyme further denies each allegation contained in Lupin's Counterclaim that was not specifically admitted, denied or otherwise responded to in this Answer .

/s/ George E. Brown
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 21st day of August, 2009, a copy of the foregoing

Answer to Counterclaim was sent by ECF filing to:

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/s/ George E. Brown